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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,223	11/19/2001	John E. Hogan	37-55	8201

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EXAMINER

PARKER, FREDERICK JOHN

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,223

Applicant(s)

HOGAN ET AL.

Examiner

Frederick J. Parker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60,64-67,71,84,87,91-94,98,111 and 143-173 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60,64-67,71,84,87,91-94,98,111 and 143-173 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. 08/966582, filed 9/21/01. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority

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claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.

- (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Headings are missing and should be inserted according to the above guidelines.

- 2. The disclosure is objected to because of the following informalities: page 24, line 36, the word "st p" is a typographical error. Appropriate correction is required.
- 3. The use of trademarks in the Examples has been noted in this application. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

The amendments/new claims in response to the Claim Objections of the Previous Office Action are acknowledged and appreciated, and the Examiner withdraws the objections.

Double Patenting

The terminal disclaimer in response to the Double Patenting rejections of the Previous Office Action is acknowledged and appreciated, and the Examiner withdraws the rejections.

Claim Rejections - 35 USC § 102

The arguments regarding priority dates in response to the 35 USC 102 rejections of the Previous Office Action are acknowledged and appreciated, and the Examiner withdraws the rejections. New rejections are introduced below as necessitated by additional prior art.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 60,71,87,98,143,149,154,156,158-164,169,171-173 are rejected under 35

U.S.C. 102(b) as being anticipated by Staniforth et al GB 2 253 164 (PD 2-9-1992).

Staniforth teaches to electrostatically powder coat pharmaceutical tablet cores (also encompassing pellets, capsules or spherules) and other medicinal products, e.g. implants, by applying a charged powder to an earthed or oppositely charged substrate to provide a coated substrate which is then heated by irradiation to fuse the coating. Charging of powder by corona or triboelectrically is taught on page 8, 7-13. Coating powders comprise materials which meet Applicants' definition of *active* set forth on Specification page 18, of a material which changes rate of a process in a biological environment, including the delayed release coatings on Staniforth et al page 11 and page 12, 12-18 which teaches the coating may be medicinal in nature which is rate-controlling. Such a coated product would inherently be a "unit dosage" because the product includes a specific amount / dosage of intended material. The powder further comprises "blended materials" (same as "co-processed") to meet the property criteria on pages 9-10, which

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would necessarily be "composite materials" because they meet Applicants' definition in their specification page 4, line 29+.

Claim Rejections - 35 USC § 103

The arguments regarding priority dates and arguments in response to the 35 USC 103 rejections of the Previous Office Action are acknowledged and appreciated, and the Examiner withdraws the rejections. New rejections are introduced below as necessitated by additional prior art.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 64-66, 91-94, 144-148, 150-152, 165-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al.

Staniforth et al is cited for the same reasons previously discussed, which are incorporated herein. Specific particle size distributions and other process details are not cited or anticipated by the reference.

Staniforth cites melting of components at 50-180C preferably 60-100C (p.10, 7-8) to prevent damage to the core during heating, hence heating temperatures would have approximated these ranges, dependant upon the melting characteristics of the specific powders applied for the process and desired properties of the end-use product. Thus, the ranges disclosed by the reference at least encompass those of Applicants claims 151-152. Powder particle sizes are taught to be 1-1000 microns, preferably the smaller sizes of 30-80 microns to allow even dispersion of the powder (page 9, 13-18). While particle size ranges per se are not cited, it is the Examiner's position that the skilled artisan would have modified particle size distribution to form the most effectively packed coating for a desired application per claims 64-67, 91-94, 144-

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147,165-168. Resistivity of the powder is cited to be 10^6 - 10^{24} , preferably 10^{10} - 10^{14} to facilitate charge maintenance, overlapping the range of claim 148. The subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made if the overlapping portion of the heating temperatures, particle sizes, and resistivities disclosed by the reference were selected because overlapping ranges have been held to be a prima facie case of obviousness, see *In re Wortheim* 191 USPQ 90.

As to claim 150, the reference encompasses a dielectric powders which are capable of polarization/ charging, meeting the conventional meaning of an electret.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the process of Staniforth et al and modifying heating temperatures, particle sizes, and other process variables in order to optimize the electrostatically applied coating for any given end-use application.

8. Claims 153,157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al in view of Sturzenegger et al US 4128445.

Staniforth et al is cited for the same reasons previously discussed, which are incorporated herein. Additional active materials in the powder are not disclosed.

Sturzenegger et al teaches to electrostatically powder coat medical web substrates to establish unit dosages, using powder particle sizes of 1-100 microns (col. 16, 39-57). The powder contains active ingredients as well as inert fillers and other conventional additives, e.g. disintegrators. Medicinally active materials include anti-inflammatories, decongestants, nutritional substances/ vitamins, etc per claim 157. While Sturzenegger et al is related to webs,

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since Staniforth et al does not exclude webs, but recognizes the process for substrates other than tablets, there is at least the suggestion of using other materials and substrates in the process of Staniforth, such as those of Sturzenegger et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the process of Staniforth et al by incorporating medically active ingredients into coating electrostatically applied onto the tablet core to provide the advantage of a dosage of consistence amount and release.

9. Claims 84,11,155,170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al in view of Zador et al US 5011513.

Staniforth et al is cited for the same reasons previously discussed, which are incorporated herein. Applying powder moving upward from a source to a supported substrate is not expressly cited.

Staniforth does teach an electrostatic powder cloud coating process in which the powder is fed downward by gravity to the intended substrate. Zador teaches the use of an upward electrostatic propulsion method to apply abrasive powder grains to a substrate in a substantially uniform distribution, in which the grains are propelled upward to the substrate. Zador also teaches in col. 9, 57-65 the equivalence of conventional electrostatic upward propulsion or gravity deposition (e.g. Staniforth's method). Since both rely on electrostatically applying powder/ particles to a substrate in a cloud-type manner, even though one is with gravity and the other is against gravity, nonetheless the outcomes would have been expected to be similar, particularly given the equivalence taught by Zador. While Zador is for abrasive grains rather than pharmaceutical uses, it is the Examiner's position that they are analogous art because they are in the same field of

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endeavor, are simply variations of a given electrostatic powder coating process, and are equivalent means of electrostatic powder coating.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the process of Staniforth et al by substituting the recited powder coating means with the upward electrostatic propulsion means of Zador et al because Zador establishes the equivalence of both means for electrostatically applying powder coatings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick J. Parker whose telephone number is 571/ 272-1426. The examiner can normally be reached on Mon-Thur. 6:15am -3:45pm, and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on 571/272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Frederick J. Parker
Primary Examiner
Art Unit 1762

fjp